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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William J. McNichol, Jr., Esquire
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,698	PATEL ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/05/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *19-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 06/05/2006; and IDS filed 03/22/2006.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 05, 2006 has been entered.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to drug delivery system comprising pad, container, and an emulsion comprising insoluble active ingredient classified in class 424, subclass 449.

II. Claims 19-33, drawn to drug delivery system comprising pad, container, and a liquid composition comprising benzoyl peroxide, starch, carbomer, disodium EDTA, water, glycerin, sodium hydroxide, zinc lactate, glycolic

acid, C_{12}- C_{15} alkyl benzoate, cetearyl alcohol, dimethicone, glyceryl stearate/PEG 100 stearate, steareth 2, steareth 20, and polysorbate 20 classified in class 424, subclass 449.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different composition because invention I requires water insoluble active ingredient in an emulsion while invention II does not require an emulsion and requires one specific active agent, and on the other hand invention I does not require all the I ingredients required by invention II. Additionally the different inventions will have different functions as implied by the different compositions. The prior art that anticipates invention I may not anticipates invention II.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Ms. Tamara Yorita on June 14, 2006 a provisional election was made with traverse to prosecute the invention of group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action.

7. Claims 19-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-18 are included in the prosecution.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to insoluble active ingredient in an emulsion. The specification on paragraph 12, applicants disclose "insoluble drug including but not limited to prodrugs, herbal medicines, traditional medicines, and active cosmetic ingredients". There is no definition given to these medicines and active ingredients. The specification gives no guidance to one of ordinary skill in the art to the insoluble active ingredients. The specification defines one insoluble drug: benzoyl peroxide (BPO). The expression "insoluble drug in emulsion" does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. Claims employing language at the point of novelty, such as applicants' "insoluble drugs in an emulsion", neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The insoluble drug could encompass myriad of insoluble drugs and applicants claimed

"insoluble drugs in an emulsion" represents only an invitation to experiment regarding possible drugs.

11. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using BPO, does not reasonably provide enablement for the use of all insoluble drugs in an emulsion. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is delivery system comprising pad, container and composition comprising insoluble active ingredient in an emulsion.

The breadth of the claims: The claims are very broad. The claims encompass all insoluble active agent and drug in an emulsion including prodrugs, herbal medicines, traditional medicines, and active cosmetic ingredient, also claimed in claim 17.

The state of the prior art: The state of the art does not recognize all insoluble drugs or active ingredients in an emulsion in a pad, but recognized BPO in an emulsion in a pad, US 6,338,855.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on all insoluble prodrugs, herbal medicines, traditional medicines, and active cosmetic ingredients. It is not obvious from the disclosure of BPO if all other insoluble prodrugs herbal medicines, traditional medicines, and active cosmetic ingredients will work. *In re Dreshfield,* 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re*

Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to insoluble prodrugs, herbal medicines, traditional medicines, and active cosmetic ingredients delivery makes practice the invention unpredictable in terms of what insoluble drugs can be delivered in an emulsion in a pad by cutaneous or transdermal application from the pad.

The presence or absence of working examples: The specification discloses only BPO. No working examples to show using any other insoluble prodrugs, herbal medicines, traditional medicines, and active cosmetic ingredients. Therefore, the specification has enabled only BPO, but not all insoluble drugs and active agents.

The quantity of experimentation necessary: The art demonstrates BPO in pad for cutaneous administration and not all the prodrugs, all herbal medicines, all traditional medicines, and all active cosmetic ingredients. Therefor, the practitioner would turn to trial and error experimentation to practice the instant composition delivering insoluble drugs and prodrugs in an emulsion into the skin from pad without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, applicant recite "insoluble drugs", is it water insoluble, alcohol insoluble, fat insoluble, etc.?

With regard to claim 3, the claim recite that "the benzoyl peroxide comprises particles of less than---", recourse to the specification, page 4, paragraph 13, applicants refer to the particle size as the size of the droplet of the discontinuous phase of the emulsion in the continuous phase, and not the particle size of the BPO, and no definition regarding BPO comprising particles.

Regarding claim 17, the expressions "prodrugs", "herbal medicines", "traditional medicines", and "active cosmetic ingredient" do not set forth the metes and bounds of the claim. Recourse to the specification does not define the expressions.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 2, 6, 7, 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,562,642 ('642).

US '642 discloses a non-woven pad impregnated by dermatologically active ingredients wherein the non-woven material is capable of absorbing a flowable liquid composition of the active ingredients (abstract; col.4, lines 37-39; col.5, lines 25-31; col.8, lines 21-34). The active ingredients include benzoyl peroxide, which is inherently insoluble, and antibiotic including neomycin, clindamycin, erythromycin, or cortisone which read on claim 17-18 (col.10, lines 46-52). The composition is an emulsion (col.14, lines 38-40; table VI; col.20, lines 15-35). The pad is contained in a container comprising aluminum foil layer in contact or sealed with thermoplastic layer that is sealable by heat, which packaging is not prone to premature rupture but provides ready dispensing of the package contents (col.3, lines 55-57; col.8, lines 45-59). The pad can be impregnated by antifungal agent or other dermatologically active agents (col.11, lines 50-52). Viscosity is inherent to a specific composition.

16. Claims 1, 2, 6, 7, 14, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,183,766 ('766).

US '766 discloses non-woven pad impregnated by composition in the form of emulsion comprising: benzoyl peroxide (col.12, line 56); glycerin (col.11, line 42); antifungal agent (col.12, line 64); and glycerin, perfumes, erythromycin, which reads on claims 17-18 (col.11, lines 47; col.12 lines 17, 58-59; col.13, lines 44-45). The pads are contained in a container (col.17, lines 41-45). The preferred droplet size of the emulsion is from 0.2 to 200 microns (col.4, lines 24-28). Viscosity is inherent to a specific composition.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 3-5, 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '642.

The teachings of US '642 are discussed above. US '642 does not teach the BPO in an emulsion, the claimed particle size and viscosity, or the woven material.

US '642 suggests the use of BPO for skin application from a pad and also suggests the emulsion. Therefore, one having ordinary skill in the art at the time of the

invention would have been motivated to include BPO in the emulsion of table VI, motivated by the skill of versed artisan that BPO is effective to treat acne, with reasonable expectation of having emulsion comprising BPO impregnated into a pad wherein the emulsion is delivered cutaneously and effective against acne.

The claimed particle sizes and viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests the low viscosity of the liquid composition as implied by the flowability of the composition in order to be absorbed into the non-woven pad.

The woven material does not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the non-woven pad impregnated with composition comprising benzoyl peroxide in an emulsion in a container as disclosed by the reference, and adjust the viscosity motivated by the desire of the reference to obtain flowability of the composition suitable for the composition to be absorbed into the pad, as also desired by applicants, with reasonable expectation of having pad that deliver active benzoyl peroxide when wiped to the skin.

20. Claims 3-5, 8-13 rejected under 35 U.S.C. 103(a) as being unpatentable over US '766.

The teachings of US '766 are discussed above. US '766 does not teach the BPO in an emulsion, the claimed viscosity, or the woven material.

US '766 suggests the use of BPO for skin application from a pad and also suggests the emulsion. Therefore, one having ordinary skill in the art at the time of the invention to include BPO in the emulsion, motivated by the skill of versed artisan that BPO is effective antimicrobial agent and effective to treat acne, with reasonable expectation of having emulsion comprising BPO impregnated into a pad wherein the emulsion is effective against bacteria and acne.

The claimed viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests adding viscosity enhancer to the composition impregnated into pad.

The woven material does not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the non-woven pad impregnated with composition comprising benzoyl peroxide in an emulsion in a container as disclosed by the reference, and adjust the viscosity motivated by the desire of the reference to obtain viscous fluid to be absorbed into the pad, as also desired by applicants, with reasonable expectation of having pad that deliver active benzoyl peroxide when wiped to the skin.

21. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '624 in view of US '766.

The teachings of the references are discussed above, however, US '642 does not teach the particle size as claimed in claims 4 and 5.

US '766 teaches particles sizes of the emulsion are preferred to be between 0.2 and 200 micron.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the emulsion disclosed by US '642 with particle sizes between 0.2 and 200 micron motivated by the teaching of US '766 that this range of droplet size is preferred for emulsion impregnated in a pad to deliver active agents to the skin, with reasonable expectation of having emulsion having droplet sizes of 0.2 and 200 micron impregnated in a pad that deliver active ingredients to the skin with great success.

22. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '766 in view of US '642.

The teachings of the references are discussed above, however, US '766 does not teach the package as claimed in claim 15.

US '642 teaches package as claimed in claim 15 as not prone to premature rupture but provides ready dispensing of the package contents.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pad impregnated with active agent in an emulsion

and contained in a container as disclosed by US '766, and replace the container by the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having pad containing active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

23. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,784,145 in view of US '642.

US '145 teaches nonwoven substrate impregnated with composition in the form of an emulsion comprising active agent such BPO, insoluble, erythromycin, soluble, neomycin, antifungal (abstract; col.6, lines 37-38, 45; col.7, lines 7, 14-15). The emulsion is either water/oil or oil/water emulsion (col.3, lines 35-44). The composition has viscosity preferably below 150 mPa.s in order to be suitable to impregnate the substrate (col.3, lines 24-28). The mean size of the globules of the emulsion is between 50-1000 microns in order to be suitable to impregnate the substrate (col.7, lines 63-67).

However, US '145 does not teach the impregnated substrate is contained in a container.

It is implied by the teaching of the reference that wipes and substrates impregnated with liquid composition are packaged in containers.

US '642 teaches a container for substrate impregnated with a liquid composition, as discussed above.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion as disclosed by US '145, and package the article in the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having substrate impregnated with active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

24. Claims 4, 5, and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '642 in view of US '145.

The teachings of the references are discussed above.

US '642 does not teach the particle sizes and viscosity of the emulsion, which is taught by US '145.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by US '642, and adjust the droplet sizes of the emulsion between 50-1000 microns and

the viscosity to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that these parameters are suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a packaged article comprising substrate impregnated with emulsion having particle sizes of 50-1000 micron and viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

25. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '766 in view of US '145.

The teachings of the references are discussed above.

US '766 does not teach the viscosity of the emulsion, which is taught by US '145.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by US '766, and adjust the viscosity of the emulsion to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that this viscosity is suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a packaged article comprising substrate impregnated with emulsion having viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

26. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,338,855 ('855) in view of US '642.

US '855 teaches article for delivering active agents to the skin comprises woven or nonwoven substrate impregnated with composition in the form of emulsion comprising BPO as preferred active agent, antifungal, water soluble agents (abstract; col.6, lines 13-17; col.17, lines 30-31, 42, 55-57; col.18, lines 18, 30-40; col.25, lines 66-67; col.26, lines 19-26; col.55, lines 37-67). The composition further comprises material to adjust the viscosity the composition remains on the substrate (col.49, lines 35-50).

US '855 does not teach the article in a container, or particle sizes or the viscosity of the composition.

It is implied by the teaching of the reference that wipes and substrates impregnated with liquid composition are packaged in containers.

US '642 teaches a container for substrate impregnated with a liquid composition, as discussed above.

The claimed particle sizes and viscosity do not impart patentability to the claims because the art recognized the desire to have viscosity of the impregnated composition enough to retain the composition in the pad, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion as disclosed by US '855, and package the article in the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that

this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having substrate impregnated with active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

27. Claims 4, 5, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '855 in view of US '642 and further in view of US '145.

Although the cited references recognized the importance of changing the viscosity of the composition to allow the composition to remain on the substrate, the combined teaching of US '855 and US '642 does not teach the exact particle sizes and viscosities as claimed by applicants.

US '145 teaches the same ranges of particle sizes and viscosity of the composition because and teaches that these parameters are suitable for impregnating the composition into a substrate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising woven or nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by the combined teachings of US '855 and 642, and adjust the droplet sizes of the emulsion between 50-1000 microns and the viscosity to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that these parameters are suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a

packaged article comprising substrate impregnated with emulsion having particle sizes of 50-1000 micron and viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

Response to Arguments

28. Applicant's arguments filed 06/05/2006 have been fully considered but they are not persuasive. The main gist of applicants' argument is that US '642 cannot anticipate the claims because it does not teach the claimed viscosity. Applicants argue that the examiner's argument is simply a hindsight attribution of the invention to the prior art and cannot properly form the basis for the rejection of claims 4, 5, 8-12 over US '642.

In response to the argument against the anticipatory rejection over US '642, and in view of the new ground of rejection, claim 1 does not recite any active agent or any ingredient of the emulsion, therefore, the US '642 anticipates claim 1, and the viscosity is an inherent for the specific composition. Both of US '642 recognized the desire to increase the viscosity of the composition to allow retention of the composition into the substrate.

In response to applicant's argument that the examiner's conclusion of obviousness for rejecting claim 4, 5, 8-12 over US '642 is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER